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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/797,770	02/07/97	BAROFSKY	A 4430-18

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EXAMINER	
PREBILIC, P	
ART UNIT	**PAPER NUMBER**
3738	17

DATE MAILED: 12/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/797,770	Barofsky et al
Examiner	**Group Art Unit**
Paul Prebilic	3738

☒ Responsive to communication(s) filed on *Aug 16, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24, 36-55, 74, and 76-99* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-24, 36-55, 74, and 76-99* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 47-55, the terminology of "consisting essentially of" has a confusing and indefinite scope in that it apparently does not preclude crosslinking agents used to polymerize the tropoelastin (see page 8, line 21 to page 9, line 9 of the present specification), but it does, according the Applicant's argument, preclude fibrin and polypeptides; see the 37 CFR 1.132 declaration filed July 12, 1999. It is the Examiner's position that crosslinking agents, fibrin, and polypeptides are all material to the structure and that they would be precluded by "consisting essentially of" language. In view of the Applicant's specification, however, this terminology will be interpreted as having the same scope as "comprising".

In claim 48, the terminology "tissue substrate" does not have clear antecedence from claim 47, and thus, its use renders the claim language indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24, 74, and 76-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,989,244. Although the conflicting claims are not identical, they are not patentably distinct from each other because elastin and elastin-based biomaterial is equivalent to tropoelastin biomaterial because tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin. Therefore, the term tropoelastin biomaterial, as defined in the present specification as crosslinked or polymerized tropoelastin, is actually elastin or elastin-based material. For these reasons, the claim sets are clearly obvious over each other.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24, 36-46, 74, and 76-99 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014).

Gregory et al is viewed as anticipating the present claims because crosslinked or polymerized tropoelastin is elasin even though it is not called such in the disclosure because the tropoelastin is uncrosslinked and unpolymerized percursor to elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al, especially Figure 1, page 1, lines 12-23 and page 8, line 21 to page 9, line 9. In other words, tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin. Therefore, the term tropoelastin biomaterial, as defined in the present specification as crosslinked or polymerized tropoelastin, is actually elastin or elastin-based material. For these reasons, the claims are anticipated by Gregory et al (WO).

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to

elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima fascia obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's Admission wherein the claimed process of tropoelastin polymerization reads on the natural process of elastin formation in vertebrates according to Bedell-Hogan, et al in the Journal of Biological Chemistry; see page 1, lines 12-23 of the present specification.

Claims 36-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al (US 5,628,785) wherein the claimed process of tropoelastin polymerization reads on the Schwartz et al device because tropoelastin is disclosed in the present specification as elastin which is uncrosslinked and unpolymerized. Therefore, since Schwartz et al discloses an unpolymerized and uncrosslinked elastin which is crosslinked with fibrin to form an elastin polymer, the Examiner posits that the claimed invention is anticipated thereby; see the whole document.

Claims 47, 48, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Labroo et al (US 5,428,014) wherein the terminology "consisting essentially of" does not apparently preclude crosslinking agents to polymerize tropoelastin so it is the Examiner's position that it does not necessarily eliminate other polypeptides as disclosed by Labroo et al because these other polypeptides could be construed as crosslinking agents; see the whole document especially Col. 9, lines 1-21.

Allowable Subject Matter

Claims 49-52 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

With regard to the withdrawal of the rejection of claims 47-55 over Rabaud et al, Schwartz et al and Gregory (WO), the Examiner noticed that none of these patents disclosed a tropoelastin monomer as a starting material. This monomer is different to elastin in that it is free of all crosslinking and is produced by a nutritional deficiency in a living organism; see the Applicant's present specification.

Response to Arguments

Applicant's arguments filed August 16 and July 12, 1999 have been fully considered but they are not persuasive. Specifically, the 37 CFR 1.131 declaration fails to adequately show prior invention and the 37 CFR 1.132 affidavit is unpersuasive in view of other of Applicant's arguments, the present specification and present claims.

The declaration filed on July 12, 1999 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gregory et al (WO 96/14807) reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Gregory et al (WO) reference to either a constructive reduction to practice or an actual reduction to practice. Specifically, there is no due diligence shown from the conception date before May 23, 1996 to the constructive reduction on February 7, 1997; see

MPEP 715.07(a) which is incorporated herein by reference thereto. In fact, a period of 2 days lacking activity has been held to be fatal; see In re Mulder 219 USPQ 189, 193 (Fed. Cir. 1983).

In addition, the declaration provides very little evidence such that even conception of the claimed invention is not shown; see MPEP 715.02 which is incorporated herein by reference. For example, the declaration fails to disclose anything about radiation fusion, a tissue substrate, a support member, polymerization, or an energy absorbing material even each of the present claims set forth at least one of these limitations. For this reason, conception of the claimed invention is not adequately shown to the extent that this insufficiency alone renders the declaration defective.

The declaration under 37 CFR 1.132 filed July 12, 1999 is insufficient to overcome the rejection of all pending claims based upon Rabaud et al as set forth in the last Office action because:

The arguments in the declaration are not consistent with the specification and claims which are confused thereby. Specifically, the claims set forth the language "consisting essentially of" which apparently preclude all other material components except tropoelastin. However, it is clear from the specification that the polymerization of tropoelastin takes place as a result of a crosslinking agent; see Figure 1 and page 8, line 21 to page 9, line 9. Furthermore, Applicant argues that Rabaud et al does not meet the claim language because of the presence of fibrin. For this reason, it is not clear what the language "consisting essentially of" is intended to preclude because fibrin and other monomers could be considered as immaterial as the crosslinking agent is.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738